

June 19, 2013

By Electronic Filing

Michael E. Gans
Clerk of the Court
United States Court of Appeals for the Eighth Circuit
Thomas F. Eagleton U.S. Courthouse
111 South 10th Street
St. Louis, Missouri 63102

Re: United States ex rel. Laurie Simpson v. Bayer Healthcare, et al., No. 12-2979
Letter Pursuant to Federal Rule of Appellate Procedure 28(j), concerning
Oral Argument on June 12, 2013

Dear Mr. Gans:

During oral argument I noted that the United States might file a Statement of Interest in Ms. Simpson's other action against Bayer, United States ex rel. Simpson v. Bayer Corporation et al., No. 05-3895, concerning the drugs Trasylol and Avelox. Yesterday, the United States did file such a Statement of Interest, by cover letter. (Exs. 1 & 2.)

Simpson's Trasylol and Avelox allegations parallel her Baycol claims in alleging material misbranding and kickbacks. The United States explains that a drug manufacturer's illegal promotion and marketing of a drug may serve as the basis for a lawsuit under the FCA where the claim for payment from a healthcare provider was not "legally reimbursable," and that the statutory scheme for Medicare sets forth "one way" in which such claims fail to meet that standard. (Ex. 2 at 3-5.) The relator need not show that the "alleged regulatory violations would have resulted in the withdrawal of regulatory approval" for the drug at issue, only that the government would regard the prescription claims as "non-reimbursable." (Id. at 3 n.1.) In addition, once an underlying violation of the Anti-Kickback Statute is established, "all claims tainted by those kickbacks are false as a matter of law because they violate a fundamental condition of payment." (Id. at 5.)

As to any requirement to allege individual false claims, the United States wrote: "When a complaint sets forth with particularity allegations of a fraudulent scheme or course of conduct allowing a plausible inference that false claims were presented to the federal government, it is not also necessary to identify specific claims because doing so adds little to the sufficiency of the complaint as a whole." (Id. at 8.)

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Contrary to Bayer's contention in its response to Ms. Simpson's prior Rule 28(j) letter, the issue on appeal regarding materiality is only whether it is plausible that the United States would consider a drug manufacturer's misleading marketing regarding safety and efficacy, and which constitutes misbranding, material to its decision to refuse or seek return of payment. The most recent Statement of Interest shows that Ms. Simpson's allegations here meet that standard.

Respectfully submitted,

/s/ Edward Normand
Edward Normand

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